

REMARKS**Telephone Interview on January 30, 2006**

Applicant wishes to thank the Examiner for his courtesy during the telephonic interview conducted between the Examiner and Applicants' attorney, Richard C. Kim, on January 30, 2006. During the interview, Mr. Kim argued that neither U.S. 5,922,284 to Kinoshita et al. (hereinafter "Kinoshita") nor U.S. 5,408,535 to Howard, III et al. (hereinafter "Howard") disclose or suggest a template having at least one window for holding a test device (e.g., a test strip), wherein the template is a separate device and not integral with the test device. The Examiner indicated that he would consider such arguments and requested that Mr. Kim prepare a written response to the final Office action, dated November 22, 2005, containing these arguments, for further consideration by the Examiner. Accordingly, Applicant submits the amendments and remarks contained herein for further consideration by the Examiner.

Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 1-5 and 8-15 as being anticipated under 35 U.S.C. § 102(b) by Kinoshita or Howard. In the final Office action, the Examiner relied on his grounds of rejection made in the first Office action dated June 9, 2005 and instructed Applicant to "[s]ee the appropriate paragraph of the 6/9/05 Office action." (Final Office Action, p. 2).

In the first Office action, dated June 9, 2005, the Examiner characterized Kinoshita as follows:

Kinoshita et al. teach a method and apparatus for performing an agglutination immunoassay. A microtiter plate (10) is moved by a driving means to pipetting station "B" where an agglutination reagent is pipetted into each well (see column 4 lines 35+). After the appropriate manipulation and time the plate (10) is moved to image station "F" that comprises a CCD camera (20) and lighting device

(22). The camera (20) is connected to control section (40), an image data memory (52) and a data processing section (50). . . . The claimed computer has been read on the taught control section (40), the claimed scanner on the taught camera (20) and *the claimed template on the taught driving means*.

(Non-final Office Action, dated June 6, 2005, p. 4) (emphasis added).

Based on the Examiner's statements above, the Examiner believes that the "driving means" disclosed by Kinoshita reads on the claimed "template." Applicant respectfully disagrees with the Examiner's characterization of Kinoshita's "driving means." Kinoshita does not provide any structural details of its "driving means" and even Kinoshita admits the driving means is "not shown." (Kinoshita, col. 4, line 57). Based on the rudimentary illustration of the driving means in Figure 1 of Kinoshita, it appears to be a conveyor belt for transporting a microtiter plate 10 from one station to another. No where within its four corners does Kinoshita disclose a template "configured to fit on a scanning surface of a scanner" and having "at least one window configured for receiving said at least one test device." Additionally, the driving means clearly does not "fit on a scanning surface of a scanner," as recited in claims 1, 8, 10 and 15. Instead, the "driving means" is merely a conveyor belt that transports a microtiter plate 10 from a pipetting station, for example, to a scanning station. This conveyor belt does not fit on a scanning surface of a scanner nor is it even configured to be placed on such a scanning surface, as recited by Applicants' claims.

Additionally, Kinoshita's driving means clearly does not include "at least one window configured for receiving said at least one test device," as recited by the claims. Indeed, such a "window" in Kinoshita's conveyor belt would make it inoperable, or at the very least, unstable for transporting devices.

In the Final Office Action, the Examiner stated that "Kinoshita et al. meets the claims by holding one test device and the instant claim language does not exclude the integration of the taught test device/template." (Final Office Action, p. 2). Based on this comment, Applicant surmises that

the Examiner believes that the microtiter plate 10 can be considered as a template which is integrated or integral with the test device and that the Applicants' claims do not preclude such integral embodiments. Applicants respectfully disagree. As originally worded, claim 1 requires "a template . . . configured for receiving said at least one test device . . ." This language requires that the template is separate from the test device because it is configured for receiving it. If the template and test device were integrated, the template would not be "configured for receiving" the test device. In order to further clarify the inherent requirement that the template is a separate device from the test device, Applicants have amended independent claims 1, 10 and 15 in a non-narrowing manner to require that the "template" or "means for holding" (claim 10) receives at least one test device only "temporarily." Thus, this language further makes clear that the test device is separate and not integral with the template because it can be placed into the template and thereafter extracted from the template after scanning is completed.

Independent claim 8 is a method claim that requires the affirmative step of "placing at least one test device into said at least one window" of the template. Therefore, claim 8 already clearly requires that the template is separate from the test device.

Because Kinoshita neither discloses nor suggests, *inter alia*, a template that is separate from the test device, nor a template having one or more windows for receiving and holding one or more test devices, nor a template configured to fit on a scanning surface of a scanner, Applicants respectfully submit that the Examiner's rejections of the claims as anticipated by Kinoshita are traversed. "It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Tech., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). "To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Industris, Inc. v. Guardian Industries Corp.* 75 F. 3d 1558, 1566 (Fed. Cir. 1996). *Chester v. Miller*, 906 F.2d 1574, 1576 n.2, 15 U.S.P.Q.2D (BNA) 1333, 1336 n.2 (Fed. Cir. 1990); *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. (BNA) 619, 621 (Fed. Cir. 1985). In the present case, Kinoshita fails to disclose either explicitly or inherently at least the limitations described

above. Accordingly, Applicant respectfully requests the Examiner to withdraw his rejection of the pending claims as anticipated by Kinoshita.

Howard teaches a video test strip reader that uses a video imager or camera. The Examiner states that the reading field (14), upon which individual test strips are placed, reads on the claimed template. However, like Kinoshita, Howard does not disclose or suggest a template configured to fit on a scanning surface of a scanner. Instead, Howard's disclosed reading or viewing field 14 is an imaging surface within the field of view of an imaging device or camera (e.g., CID or CCD camera). (See, e.g., Howard, col. 5, lines 8-27). The viewing field 14 is not a template configured to be placed on a scanning surface of a scanner. Rather, the viewing field 14 is itself the surface upon which objects are imaged.

The Examiner further states that the "claimed 'window' is broad enough to be read on any supporting surface on which the test device is scanned and met by Howard et al." (Final Office Action, p. 3). Applicant respectfully disagrees. As amended, independent claims 1, 8 and 15 require that the window is formed in a template configured to fit on a scanning surface, and "has a shape corresponding to the shape of the test device so as securely maintain the test device in a fixed position during scanning." Howard's viewing field 14 is not a window formed in a template that has a shape corresponding to the shape of a test device so as to maintain the test device in a fixed location. In Howard's apparatus, a test device may easily move from one portion of the viewing field 14 to another portion because there are no side retaining walls or boundaries of a window that hold and maintain a test device in a fixed position. Thus, as amended, Applicant's claimed "window" is clearly not broad enough to be read on any supporting surface. Rather, the "window" must be formed in a template that is placed on a supporting surface of a scanner and has a shape corresponding to a test device in order to securely hold the test device within the window. In this way, the invention provides for automatic and reliable scanning of test devices (e.g., test strips) using relatively inexpensive general purpose scanners and avoids the need for expensive prior art imaging systems such as those disclosed by Howard (and Kinoshita).

Since claim 10 is a means-plus-function claim, it is limited to the corresponding structure and equivalents thereof as disclosed in the specification, namely, a template configured to be placed on a scanning surface and having one or more shaped windows to securely hold one or more test devices therein, and equivalents thereof. As mentioned above, Howard does not disclose, teach, or suggest any structures or equivalents to the structures disclosed in the present specification. *See, e.g.*, ¶¶ 6, 7, and 19-22 of the patent application and figures 1, 2A, and 2B.

Because Howard does not disclose, either explicitly or implicitly, at least the claim limitations discussed above, Howard cannot anticipate any of the independent claims 1, 8, 10 and 15. Accordingly, Applicant respectfully requests the Examiner to withdraw his rejection of the pending claims as anticipated by Howard.

In light of the above remarks demonstrating the novelty of independent claims 1, 8, 10, and 15 over Kinoshita and Howard, Applicants submit these claims are now in condition for allowance. Similarly, dependent claims 2-5, 9, and 11-14, which depend from claims 1, 8, 10 and 15, respectively, are also in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

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In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 532812000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 22, 2006

Respectfully submitted,

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